

EW 5/10/97  
JF-15**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**Food and Drug Administration  
7200 Lake Ellenor Drive  
Orlando, FL 32809**WARNING LETTER**

FLA-97-56

May 8, 1997

Jorge Jimenez, President  
Community Medical Equipment Corp.  
c/o The Abilene Company  
4050 S.W. 11th Terrace  
Ft. Lauderdale, Florida 33315

Dear Mr. Jimenez:

Inspection of your medical gas filling operation located at 4368 N. Federal Highway, Ft. Lauderdale, Florida, on April 22 and 24, 1997, by FDA investigators Bonita S. Chester and Philippe L. Noisin, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations for drugs [Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the testing and release for distribution of compressed medical oxygen causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Inspection revealed there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality, in that you have failed to test each component lot of bulk oxygen received to determine conformance with appropriate specifications prior to use, or in lieu of testing, receive a valid certificate of analysis from your supplier and conduct an identity test. The [REDACTED] Analyzer used by your firm is not an acceptable test device for oxygen purity in that the accuracy of the device is  $\pm 2\%$  which is not equivalent to the USP test accuracy of  $\pm 0.1\%$ . Refilled cylinders of compressed medical Oxygen USP are not being testing for purity and identity prior to release for distribution.

Written procedures are not established for production and process controls designed to assure that your medical oxygen products have the identity, strength, quality, and purity they are represented to possess. For example, no written procedures are established for calibration and maintenance of equipment, labeling, handling of complaints, employee training, or supervision.

Jorge Jimenez, President  
Page 2  
May 8, 1997

Your written procedure for cylinder filling and testing is inadequate in that it fails to provide instructions for completion of all required manufacturing steps in the transfilling operation.

Batch production and control records are incomplete, inaccurate, and fail to document that each significant step in the manufacturing operation was completed, such as all required pre and post fill cylinder inspections and testing. All batch records reviewed document oxygen purity test results of 100% and dead ring tests being performed on aluminum cylinders. The oxygen receiving log also documents 100% oxygen purity test results on all bulk oxygen received. Records documenting calibration and maintenance of equipment are not maintained and there is no assurance that your transfill operator (manager) has been adequately trained.

Review of labeling used on cylinders of compressed medical oxygen filled by your firm reveals the products to be misbranded within the meaning of Sections 502(a), 502(b)(1) and (2), 502(e)(1)(A)(i), and 503(b)(4) of the Act. Some labels bear the unqualified names of other firm's, such as Puritan Bennett and Mada Medical Equipment, in addition to the name of your firm. Some labels fail to bear the place of business of your firm. Except as provided in 21 CFR 201.1(h)(1), no person other than the manufacturer, packer, or distributor may be identified on the label of a drug product. As the refiller, your firm is considered to be the manufacturer. Therefore, only your firm's name and place of business should appear on the label. If the distributor is named on the label, the name must be qualified in accordance with 21 CFR 201.1(h)(5). Some labels also fail to bear an accurate statement of the quantity of contents, the established name of the product as it appears in the official compendium (Oxygen USP produced by the air liquefaction process), and the statement "Caution: Federal law prohibits dispensing without prescription". In addition, labels on some cylinders are illegible and in need of replacement.

With respect to the above referenced 502(b)(2) violation, the contents of cylinders may be expressed in terms of the available volume of Oxygen USP in liters at 70° F (21.1° C) and one (1) atmosphere.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

Mr. Jorge Jimenez  
Page 3  
May 8, 1997

In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the CGMP regulations so that a verification inspection can be scheduled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. As president and owner, it is your responsibility to ensure that all medical gas products you repack and distribute are in compliance with the Act and the requirements of the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,

*Douglas D. Tolen* / E/kt  
Douglas D. Tolen  
Director, Florida District

cc: Barry J. Berger, Manager  
Community Medical Equipment Corp.  
4368 N. Federal Highway  
Ft. Lauderdale, Florida 33308